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HOUSE SUBSTITUTE

FOR

SENATE COMMITTEE SUBSTITUTE

FOR

SENATE BILL NO. 1026

AN ACT

To repeal section 376.1219, RSMo, and to enact in lieu thereof three new sections relating to health insurance coverage for cancer treatment and prevention and certain inherited diseases.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF MISSOURI, AS FOLLOWS:

Section A. Section 376.1219, RSMo, is repealed and three new sections enacted in lieu thereof, to be known as sections 376.429, 376.1219, and 376.1253, to read as follows:

376.429. 1. All health benefit plans, as defined in section 376.1350, that are delivered, issued for delivery, continued or renewed on or after August 28, 2002, and providing coverage to any resident of this state shall provide coverage for routine patient care costs as defined in subsection 6 of this section incurred as the result of phase III or IV of a clinical trial that is approved by an entity listed in subsection 4 of this section and is undertaken for the purposes of the prevention, early detection, or treatment of cancer.

2. In the case of treatment under a clinical trial, the

EXPLANATION-Matter enclosed in bold-faced brackets [thus] in the above bill is not enacted and is intended to be omitted from the law. Matter in boldface type in the above law is new proposed language.

treating facility and personnel must have the expertise and training to provide the treatment and treat a sufficient volume of patients. There must be equal to or superior, noninvestigational treatment alternatives and the available clinical or preclinical data must provide a reasonable expectation that the treatment will be superior to the noninvestigational alternatives.

3. Coverage required by this section shall include coverage for routine patient care costs incurred for drugs and devices that have been approved for sale by the Food and Drug Administration (FDA), regardless of whether approved by the FDA for use in treating the patient's particular condition, including coverage for reasonable and medically necessary services needed to administer the drug or use the device under evaluation in the clinical trial.

4. Subsections 1 and 2 of this section requiring coverage for routine patient care costs shall apply to clinical trials that are approved or funded by one of the following entities:

(1) One of the National Institutes of Health (NIH);

(2) An NIH Cooperative Group or Center as defined in subsection 7 of this section;

(3) The FDA in the form of an investigational new drug application;

(4) The federal Departments of Veterans' Affairs or

Defense;

(5) An institutional review board in this state that has an appropriate assurance approved by the Department of Health and Human Services assuring compliance with and implementation of regulations for the protection of human subjects (45 CFR 46); or

(6) A qualified research entity that meets the criteria for NIH Center support grant eligibility.

5. An entity seeking coverage for treatment, prevention, or early detection in a clinical trial approved by an institutional review board under subdivision (5) of subsection 4 of this section shall maintain and post electronically a list of the clinical trials meeting the requirements of subsections 2 and 3 of this section. This list shall include: the phase for which the clinical trial is approved; the entity approving the trial; whether the trial is for the treatment of cancer or other serious or life threatening disease, and if not cancer, the particular disease; and the number of participants in the trial. If the electronic posting is not practical, the entity seeking coverage shall periodically provide payers and providers in the state with a written list of trials providing the information required in this section.

6. As used in this section, the following terms shall mean:

(1) "Cooperative group", a formal network of facilities that collaborate on research projects and have an established

NIH-approved Peer Review Program operating within the group, including the NCI Clinical Cooperative Group and the NCI Community Clinical Oncology Program;

(2) "Multiple project assurance contract", a contract between an institution and the federal Department of Health and Human Services (DHHS) that defines the relationship of the institution to the DHHS and sets out the responsibilities of the institution and the procedures that will be used by the institution to protect human subjects;

(3) "Routine patient care costs", shall include coverage for reasonable and medically necessary services needed to administer the drug or device under evaluation in the clinical trial. Routine patient care costs include all items and services that are otherwise generally available to a qualified individual that are provided in the clinical trial except:

(a) The investigational item or service itself;

(b) Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient; and

(c) Items and services customarily provided by the research sponsors free of charge for any enrollee in the trial.

7. For the purpose of this section, providers participating in clinical trials shall obtain a patient's informed consent for participation on the clinical trial in a manner that is

consistent with current legal and ethical standards. Such documents shall be made available to the health insurer upon request.

8. The provisions of this section shall not apply to a policy, plan or contract paid under Title XVIII or Title XIX of the Social Security Act.

376.1219. 1. Each policy issued by an entity offering individual and group health insurance which provides coverage on an expense-incurred basis, individual and group health service or indemnity type contracts issued by a nonprofit corporation, individual and group service contracts issued by a health maintenance organization, all self-insured group health arrangements to the extent not preempted by federal law, and all health care plans provided by managed health care delivery entities of any type or description, that are delivered, issued for delivery, continued or renewed in this state on or after September 1, 1997, shall provide coverage for formula and low protein modified food products recommended by a physician for the treatment of a patient with phenylketonuria or any inherited disease of amino and organic acids who is covered under the policy, contract, or plan and who is less than six years of age.

2. [The health care service required by this section shall not be subject to any greater deductible or co-payment than other similar health care services provided by the policy, contract or

plan.] For purposes of this section, "low protein modified food products" means foods that are specifically formulated to have less than one gram of protein per serving and are intended to be used under the direction of a physician for the dietary treatment of any inherited metabolic disease. Low protein modified food products do not include foods that are naturally low in protein.

3. The coverage required by this section may be subject to the same deductible for similar health care services provided by the policy, contract, or plan as well as a reasonable coinsurance or copayment on the part of the insured, which shall not be greater than fifty percent of the cost of the formula and food products, and may be subject to an annual benefit maximum of not less than five thousand dollars per covered child. Nothing in this section shall prohibit a carrier from using individual case management or from contracting with vendors of the formula and food products.

[3.] 4. This section shall not apply to a supplemental insurance policy, including a life care contract, accident-only policy, specified disease policy, hospital policy providing a fixed daily benefit only, Medicare supplement policy, long-term care policy, or any other supplemental policy as determined by the director of the department of insurance.

376.1253. 1. Each physician attending any patient with a newly diagnosed cancer shall inform the patient that the patient

has the right to a referral for a second opinion by an appropriate board-certified specialist prior to any treatment. If no specialist in that specific cancer diagnosis area is in the provider network, a referral shall be made to a nonnetwork specialist in accordance with this section.

2. Each health carrier or health benefit plan, as defined in section 376.1350, that offers or issues health benefit plans which are delivered, issued for delivery, continued or renewed in this state on or after January 1, 2003, shall provide coverage for a second opinion rendered by a specialist in that specific cancer diagnosis area when a patient with a newly diagnosed cancer is referred to such specialist by his or her attending physician. Such coverage shall be subject to the same deductible and coinsurance conditions applied to other specialist referrals and all other terms and conditions applicable to other benefits, including the prior authorization and/or referral authorization requirements as specified in the applicable health insurance policy.

3. The provisions of this section shall not apply to a supplemental insurance policy, including a life care contract, accident-only policy, specified disease policy, hospital policy providing a fixed daily benefit only, Medicare supplement policy, long-term care policy, short-term major medical policies of six months or less duration, or any other supplemental policy as

determined by the director of the department of insurance.